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Constantineau et al.

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(54) **BALLISTIC MICRONEEDLE INFUSION DEVICE**

(71) Applicant: **Becton, Dickinson and Company**, Franklin Lakes, NJ (US)

(72) Inventors: **Cole Constantineau**, Cambridge, MA (US); **Ryan Schoonmaker**, San Marcos, CA (US); **Michel Bruehwiler**, Newton, MA (US); **Eric Bené**, Lynn, MA (US)

(73) Assignee: **Becton, Dickinson and Company**, Franklin Lakes, NJ (US)

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(51) **Int. Cl.**

A61B 17/34	(2006.01)
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A61M 5/142	(2006.01)

(52) **U.S. Cl.**

CPC ***A61M 5/158*** (2013.01); *A61M 2005/14264* (2013.01); *A61M 2005/1585* (2013.01); *A61M 2005/1586* (2013.01); *A61M 2205/0216* (2013.01)

(58) **Field of Classification Search**

CPC A61M 5/158; A61M 2005/1585; A61M 2005/1586; A61M 2205/0216; A61M 2005/14264

USPC 604/164.01, 164.04, 164.12, 180

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,857,382 A	12/1974	Williams, Jr. et al.
3,918,355 A	11/1975	Weber
3,963,380 A	6/1976	Thomas, Jr. et al.

(Continued)

FOREIGN PATENT DOCUMENTS

EP	0 980 687	2/2000
EP	1 743 667 A2	1/2007

(Continued)

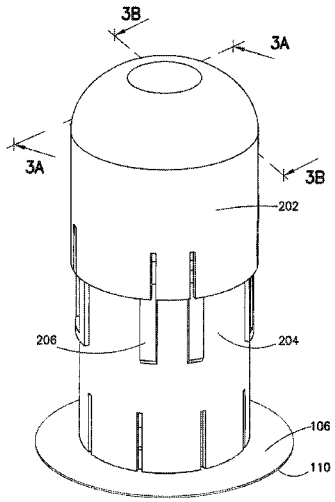
Primary Examiner — Theodore Stigell

(74) *Attorney, Agent, or Firm* — Dickinson Wright PLLC

(57) **ABSTRACT**

An infusion set has a disposable inserter that can insert a needle at a controlled rate of speed to a depth to deliver insulin or other medicament to the upper 3 mm of skin surface, and a skin securing, adhesive layer to secure the skin surface at the insertion site such that the inserter that can insert a needle without a risk of tenting of the skin surface. Position of the inserted needle can be maintained by providing a separated inner and outer hub of the infusion set that can isolate the inserted needle from external forces such that the needle can be maintained at a depth to deliver insulin or other medicament to the upper 3 mm of skin surface during normal use.

14 Claims, 9 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

4,204,538	A		5/1980	Cannon
4,490,141	A		12/1984	Lacko et al.
4,685,902	A		8/1987	Edwards et al.
4,723,947	A		2/1988	Konopka
4,734,092	A		3/1988	Millerd
4,755,173	A		7/1988	Konopka et al.
4,894,054	A	*	1/1990	Miskinyar 604/136
5,176,662	A		1/1993	Bartholomew et al.
5,226,899	A		7/1993	Lee et al.
5,242,406	A		9/1993	Gross et al.
5,257,980	A		11/1993	Van Antwerp et al.
5,453,099	A		9/1995	Lee et al.
5,522,803	A		6/1996	Teissen-Simony
5,536,249	A		7/1996	Castellano et al.
5,545,143	A		8/1996	Fischell
5,545,152	A		8/1996	Funderburk et al.
5,593,390	A		1/1997	Castellano et al.
5,728,074	A		3/1998	Castellano et al.
5,800,420	A		9/1998	Gross et al.
5,820,602	A		10/1998	Kovelman et al.
5,851,197	A		12/1998	Marano et al.
5,858,001	A		1/1999	Tsals et al.
5,858,005	A		1/1999	Kriesel
5,925,021	A		7/1999	Castellano et al.
5,957,895	A		9/1999	Sage et al.
5,968,011	A		10/1999	Larsen et al.
5,980,506	A		11/1999	Mathiasen
6,017,328	A		1/2000	Fischell et al.
6,056,718	A		5/2000	Funderburk et al.
6,068,615	A		5/2000	Brown et al.
6,074,369	A		6/2000	Sage et al.
6,086,575	A		7/2000	Mejslov
6,093,172	A		7/2000	Funderburk et al.
6,110,148	A		8/2000	Brown et al.
6,123,690	A		9/2000	Mejslov
6,132,400	A		10/2000	Waldenburg
6,175,752	B1		1/2001	Say et al.
6,206,134	B1		3/2001	Stark et al.
6,254,586	B1		7/2001	Mann et al.
6,272,364	B1		8/2001	Kurnik
6,275,717	B1		8/2001	Gross et al.
6,277,627	B1		8/2001	Hellinga
6,293,925	B1		9/2001	Safabash et al.
6,302,866	B1		10/2001	Marggi
6,352,523	B1		3/2002	Brown et al.
6,355,021	B1		3/2002	Nielsen et al.
6,391,005	B1		5/2002	Lum et al.
6,485,461	B1		11/2002	Mason et al.
6,520,938	B1		2/2003	Funderburk et al.
6,521,446	B2		2/2003	Hellinga
6,544,212	B2		4/2003	Galley et al.
6,546,269	B1		4/2003	Kurnik
6,551,276	B1		4/2003	Mann et al.
6,558,351	B1		5/2003	Steil et al.
6,565,509	B1		5/2003	Say et al.
6,576,430	B1		6/2003	Hsieh et al.
6,579,267	B2		6/2003	Lynch et al.
6,589,229	B1		7/2003	Connelly et al.
6,607,509	B2		8/2003	Bobroff et al.
6,656,158	B2		12/2003	Mahoney et al.
6,656,159	B2		12/2003	Flaherty
6,669,669	B2		12/2003	Flaherty et al.
6,692,457	B2		2/2004	Flaherty
6,699,218	B2		3/2004	Flaherty et al.
6,706,159	B2		3/2004	Moerman et al.
6,723,072	B2		4/2004	Flaherty et al.
6,740,059	B2		5/2004	Flaherty
6,749,560	B1		6/2004	Konstrorum et al.
6,749,587	B2		6/2004	Flaherty
6,768,425	B2		7/2004	Flaherty et al.
6,830,558	B2		12/2004	Flaherty et al.
6,830,562	B2		12/2004	Mogensen et al.
6,840,922	B2		1/2005	Nielsen et al.
6,852,104	B2		2/2005	Blomquist
6,890,319	B1		5/2005	Crocker
6,949,084	B2		9/2005	Marggi et al.
6,960,162	B2		11/2005	Saadat et al.
6,960,192	B1		11/2005	Flaherty et al.
6,977,180	B2		12/2005	Hellinga et al.
6,997,907	B2	*	2/2006	Safabash et al. 604/157
7,004,928	B2		2/2006	Aceti et al.
7,018,360	B2		3/2006	Flaherty et al.
7,029,455	B2		4/2006	Flaherty
7,052,251	B2		5/2006	Nason et al.
7,056,302	B2		6/2006	Douglas et al.
7,064,103	B2		6/2006	Pitner et al.
7,070,580	B2		7/2006	Nielsen
7,083,597	B2		8/2006	Lynch et al.
7,109,878	B2		9/2006	Mann et al.
7,128,727	B2		10/2006	Flaherty et al.
7,137,964	B2		11/2006	Flaherty
7,144,384	B2		12/2006	Gorman et al.
7,207,974	B2		4/2007	Safabash et al.
7,214,207	B2		5/2007	Lynch et al.
7,226,278	B2		6/2007	Nason et al.
7,303,543	B1		12/2007	Maule et al.
7,303,549	B2		12/2007	Flaherty et al.
7,310,544	B2		12/2007	Brister et al.
7,318,816	B2		1/2008	Bobroff et al.
7,329,239	B2		2/2008	Safabash et al.
7,354,420	B2		4/2008	Steil et al.
7,407,493	B2		8/2008	Cane
7,496,392	B2		2/2009	Alarcon et al.
7,585,287	B2		9/2009	Bresina et al.
7,699,807	B2		4/2010	Faust et al.
7,713,258	B2		5/2010	Adams et al.
7,722,595	B2		5/2010	Pettis et al.
7,731,691	B2		6/2010	Cote et al.
7,736,338	B2		6/2010	Kavazov et al.
7,879,010	B2		2/2011	Hunn et al.
7,896,844	B2		3/2011	Thalmann et al.
8,152,769	B2		4/2012	Douglas et al.
8,152,771	B2		4/2012	Mogensen et al.
8,162,892	B2		4/2012	Mogensen et al.
8,172,803	B2		5/2012	Morrissey et al.
8,172,805	B2		5/2012	Mogensen et al.
8,221,359	B2		7/2012	Kristensen et al.
8,262,618	B2		9/2012	Scheurer
8,277,415	B2		10/2012	Mounce et al.
8,285,328	B2		10/2012	Caffey et al.
8,287,467	B2		10/2012	List et al.
8,287,516	B2		10/2012	Kornerup et al.
8,306,596	B2		11/2012	Schurman et al.
8,310,415	B2		11/2012	Mclaughlin et al.
8,313,468	B2		11/2012	Geipel et al.
8,814,831	B2	*	8/2014	Constantineau et al. 604/164.01
2002/0040208	A1		4/2002	Flaherty et al.
2003/0055380	A1		3/2003	Flaherty
2003/0109829	A1		6/2003	Mogensen et al.
2003/0176852	A1		9/2003	Lynch et al.
2003/0199823	A1		10/2003	Bobroff et al.
2004/0002682	A1		1/2004	Kovelman et al.
2004/0010207	A1		1/2004	Flaherty et al.
2004/0044306	A1		3/2004	Lynch et al.
2004/0059316	A1		3/2004	Smedegaard
2004/0078028	A1		4/2004	Flaherty et al.
2004/0092865	A1		5/2004	Flaherty et al.
2004/0092878	A1		5/2004	Flaherty
2004/0116866	A1		6/2004	Gorman et al.
2004/0127844	A1		7/2004	Flaherty
2004/0153032	A1		8/2004	Garribotto et al.
2004/0158207	A1	*	8/2004	Hunn et al. 604/164.01
2004/0162521	A1		8/2004	Bengtsson
2004/0204673	A1		10/2004	Flaherty
2004/0204687	A1		10/2004	Mogensen et al.
2004/0220551	A1		11/2004	Flaherty et al.
2004/0235446	A1		11/2004	Flaherty et al.
2004/0260233	A1		12/2004	Garibotto et al.
2005/0021005	A1		1/2005	Flaherty et al.
2005/0022274	A1		1/2005	Campbell et al.
2005/0043687	A1		2/2005	Mogensen et al.
2005/0065760	A1		3/2005	Murtfeldt et al.
2005/0090784	A1		4/2005	Nielsen et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2005/0101912 A1 5/2005 Faust et al.
2005/0101932 A1 5/2005 Cote et al.
2005/0101933 A1 5/2005 Marrs et al.
2005/0113761 A1 5/2005 Faust et al.
2005/0124936 A1 6/2005 Mogensen et al.
2005/0171512 A1 8/2005 Flaherty
2005/0182366 A1 8/2005 Vogt et al.
2005/0203461 A1 9/2005 Flaherty et al.
2005/0215982 A1 9/2005 Malave et al.
2005/0222645 A1 10/2005 Malave et al.
2005/0238507 A1 10/2005 DiIanni et al.
2005/0245799 A1 11/2005 Brauker et al.
2005/0273076 A1 12/2005 Beasley et al.
2005/0283144 A1 12/2005 Shiono et al.
2006/0001551 A1 1/2006 Kraft et al.
2006/0041229 A1 2/2006 Garibotto et al.
2006/0074381 A1 4/2006 Malave et al.
2006/0122577 A1 6/2006 Poulsen et al.
2006/0129090 A1 6/2006 Moberg et al.
2006/0135913 A1 6/2006 Ethelfeld
2006/0142698 A1 6/2006 Ethelfeld
2006/0173410 A1 8/2006 Moberg et al.
2006/0178633 A1 8/2006 Garibotto et al.
2006/0200073 A1 9/2006 Radmer et al.
2006/0217663 A1 9/2006 Douglas
2006/0263839 A1 11/2006 Ward et al.
2006/0264835 A1 11/2006 Nielsen et al.
2006/0282290 A1 12/2006 Flaherty et al.
2007/0016149 A1 1/2007 Hunn et al.
2007/0021733 A1 1/2007 Hansen et al.
2007/0027427 A1* 2/2007 Trautman et al. 604/46
2007/0049865 A1 3/2007 Radmer et al.
2007/0073229 A1 3/2007 Gorman et al.
2007/0073559 A1 3/2007 Stangel
2007/0088244 A1 4/2007 Miller et al.
2007/0088271 A1 4/2007 Richards
2007/0093754 A1 4/2007 Mogensen et al.
2007/0118405 A1 5/2007 Campbell et al.
2007/0149925 A1 6/2007 Edwards et al.
2007/0191702 A1 8/2007 Yodfat et al.
2007/0219496 A1 9/2007 Kamen et al.
2008/0004515 A1 1/2008 Jennewine
2008/0021395 A1 1/2008 Yodfat et al.
2008/0051697 A1 2/2008 Mounce et al.
2008/0051698 A1 2/2008 Mounce et al.
2008/0051709 A1 2/2008 Mounce et al.
2008/0051710 A1 2/2008 Moberg et al.
2008/0051711 A1 2/2008 Mounce et al.
2008/0051714 A1 2/2008 Moberg et al.
2008/0051716 A1 2/2008 Stutz
2008/0051718 A1 2/2008 Kavazov et al.
2008/0051727 A1 2/2008 Moberg et al.
2008/0051730 A1 2/2008 Bikovsky
2008/0051738 A1 2/2008 Griffin
2008/0051765 A1 2/2008 Mounce
2008/0097321 A1 4/2008 Mounce et al.
2008/0097326 A1 4/2008 Moberg et al.
2008/0097327 A1 4/2008 Bente et al.
2008/0097328 A1 4/2008 Moberg et al.
2008/0097375 A1 4/2008 Bikovsky
2008/0097381 A1 4/2008 Moberg et al.
2008/0103483 A1 5/2008 Johnson et al.
2008/0116647 A1 5/2008 Anderson et al.
2008/0119707 A1 5/2008 Stafford
2008/0132842 A1 6/2008 Flaherty
2008/0147041 A1 6/2008 Kristensen
2008/0160492 A1 7/2008 Campbell et al.
2008/0194924 A1 8/2008 Valk et al.
2008/0215006 A1 9/2008 Thorkild
2008/0261255 A1 10/2008 Tolosa et al.
2008/0264261 A1 10/2008 Kavazov et al.
2008/0269680 A1 10/2008 Ibranyan et al.
2008/0269713 A1 10/2008 Kavazov
2008/0281297 A1 11/2008 Pesach et al.
2008/0294028 A1 11/2008 Brown
2008/0306434 A1 12/2008 Dobbles et al.
2008/0312608 A1 12/2008 Christoffersen et al.
2008/0319414 A1 12/2008 Yodfat et al.
2009/0005724 A1 1/2009 Regittnig et al.
2009/0005728 A1 1/2009 Weinert et al.
2009/0012472 A1 1/2009 Ahm et al.
2009/0062767 A1 3/2009 Van Antwerp et al.
2009/0076453 A1 3/2009 Mejlhede et al.
2009/0124979 A1 5/2009 Raymond et al.
2009/0198191 A1 8/2009 Chong et al.
2009/0198215 A1 8/2009 Chong et al.
2009/0204077 A1 8/2009 Hasted et al.
2009/0221971 A1 9/2009 Mejlhede et al.
2009/0240240 A1 9/2009 Hines et al.
2009/0254041 A1 10/2009 Krag et al.
2009/0281497 A1 11/2009 Kamen et al.
2009/0326457 A1 12/2009 O'Connor
2010/0049129 A1 2/2010 Yokoi et al.
2010/0160902 A1 6/2010 Aeschilimann et al.
2010/0217105 A1 8/2010 Yodfat et al.
2010/0222743 A1 9/2010 Frederickson et al.
2010/0286714 A1 11/2010 Gyrn et al.
2010/0291588 A1 11/2010 McDevitt et al.
2010/0298830 A1 11/2010 Browne et al.
2012/0143136 A1 6/2012 Constantineau et al.
2012/0253282 A1 10/2012 Nagel et al.
2012/0259185 A1 10/2012 Yodfat et al.
2012/0265034 A1 10/2012 Wisniewski et al.
2012/0277554 A1 11/2012 Schurman et al.
2012/0277667 A1 11/2012 Yodat et al.
2012/0277724 A1 11/2012 Larsen et al.
2012/0283540 A1 11/2012 Brüggemann
2012/0291778 A1 11/2012 Nagel et al.
2012/0293328 A1 11/2012 Blomquist
2012/0296269 A1 11/2012 Blomquist
2012/0296310 A1 11/2012 Blomquist
2012/0296311 A1 11/2012 Brauker et al.
2013/0226098 A1* 8/2013 Tokumoto et al. 604/228

FOREIGN PATENT DOCUMENTS

JP 07-178170 A 7/1995
JP 2007503435 A 2/2007
JP 2009516572 A 4/2009
JP 2010507456 A 3/2010
JP 2010533525 A 10/2010
WO WO 99-34212 7/1999
WO WO 2007-051139 5/2007
WO WO 2008/051920 A2 5/2008
WO WO 2009-021039 2/2009
WO WO 2009-021052 2/2009
WO 2010080715 A1 7/2010
WO WO 2010/085338 A1 7/2010

* cited by examiner

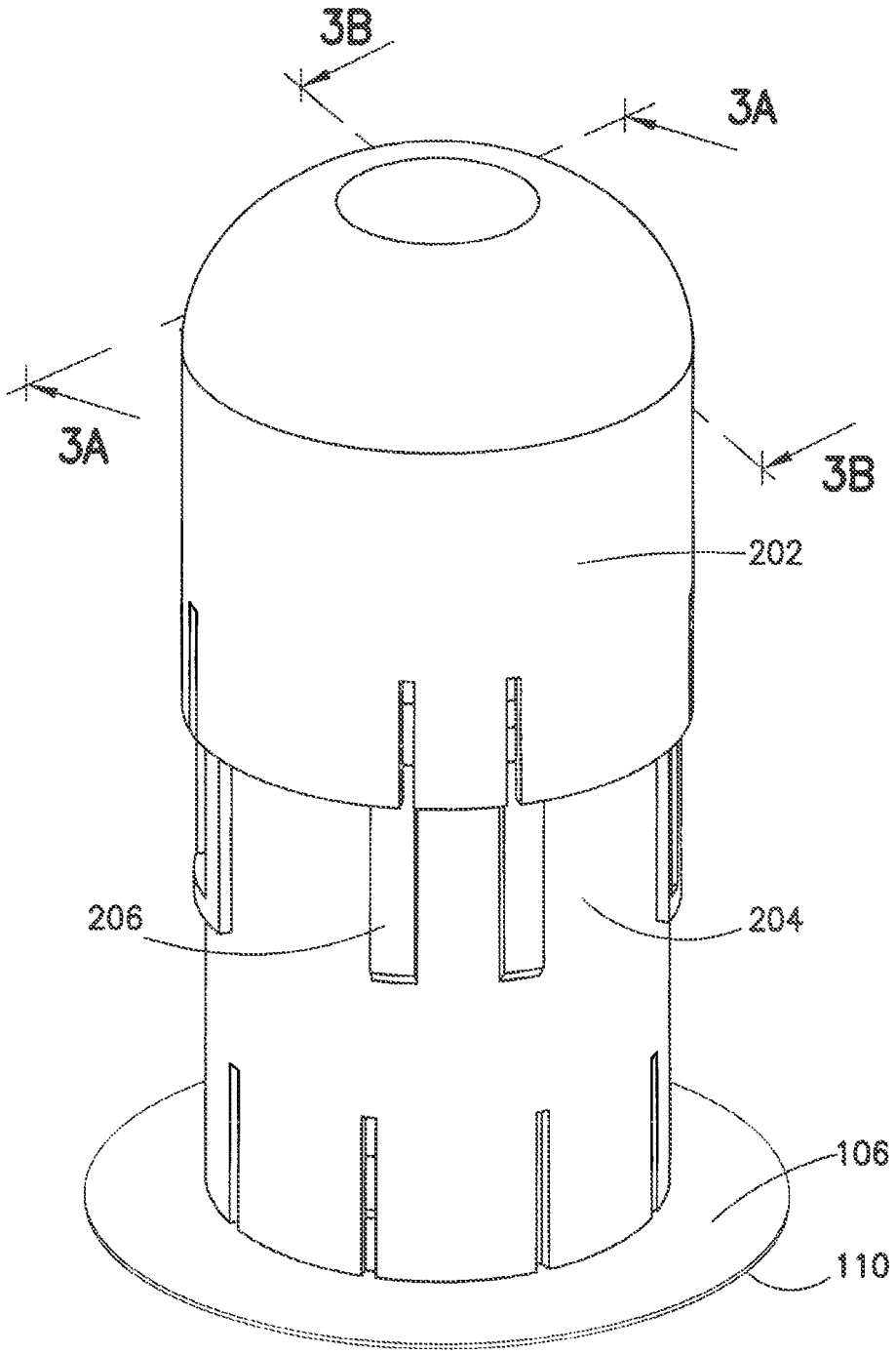


FIG. 1

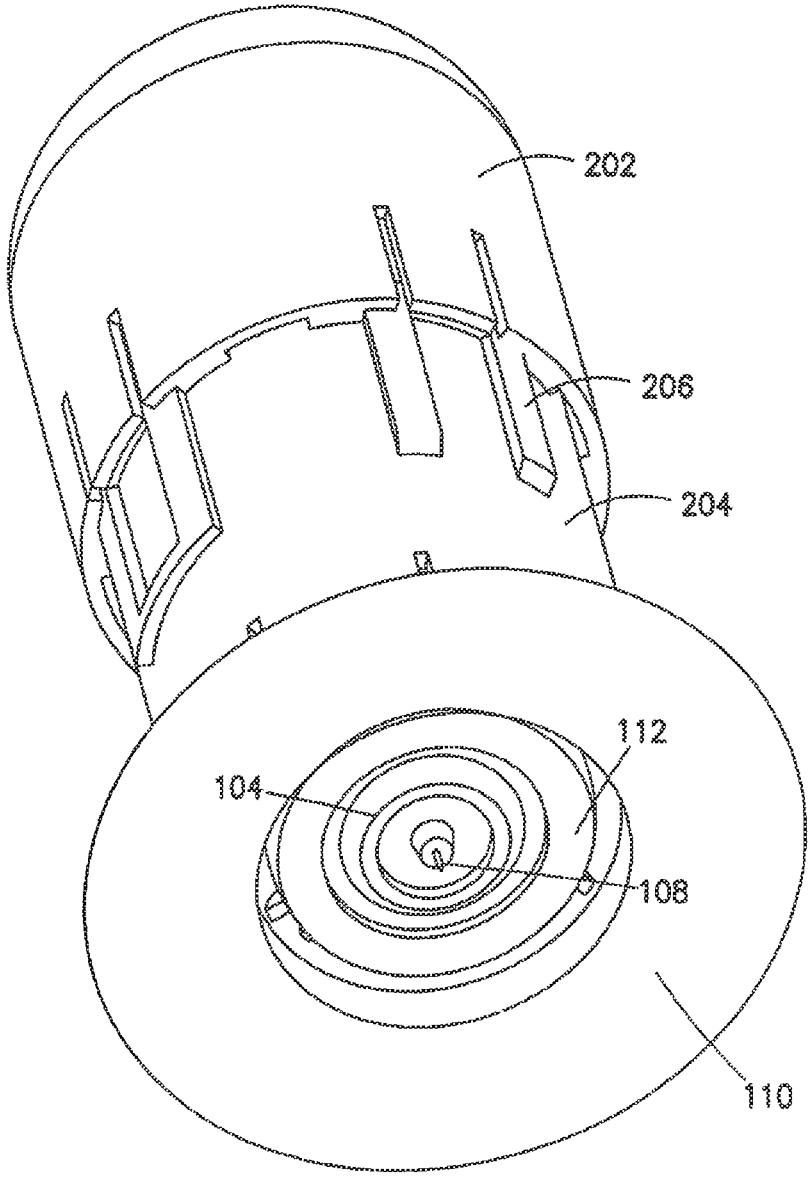


FIG.2

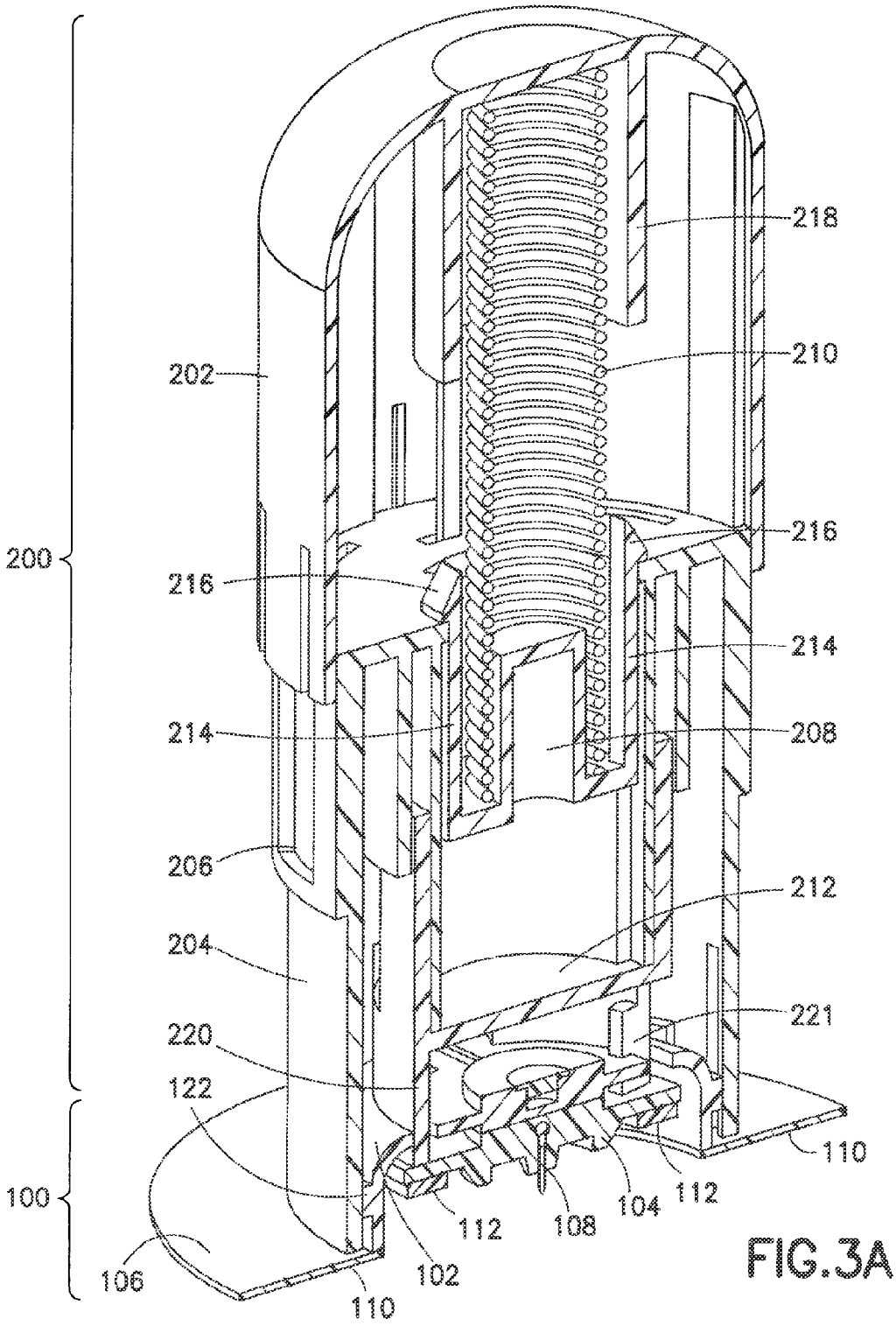

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FIG.3A

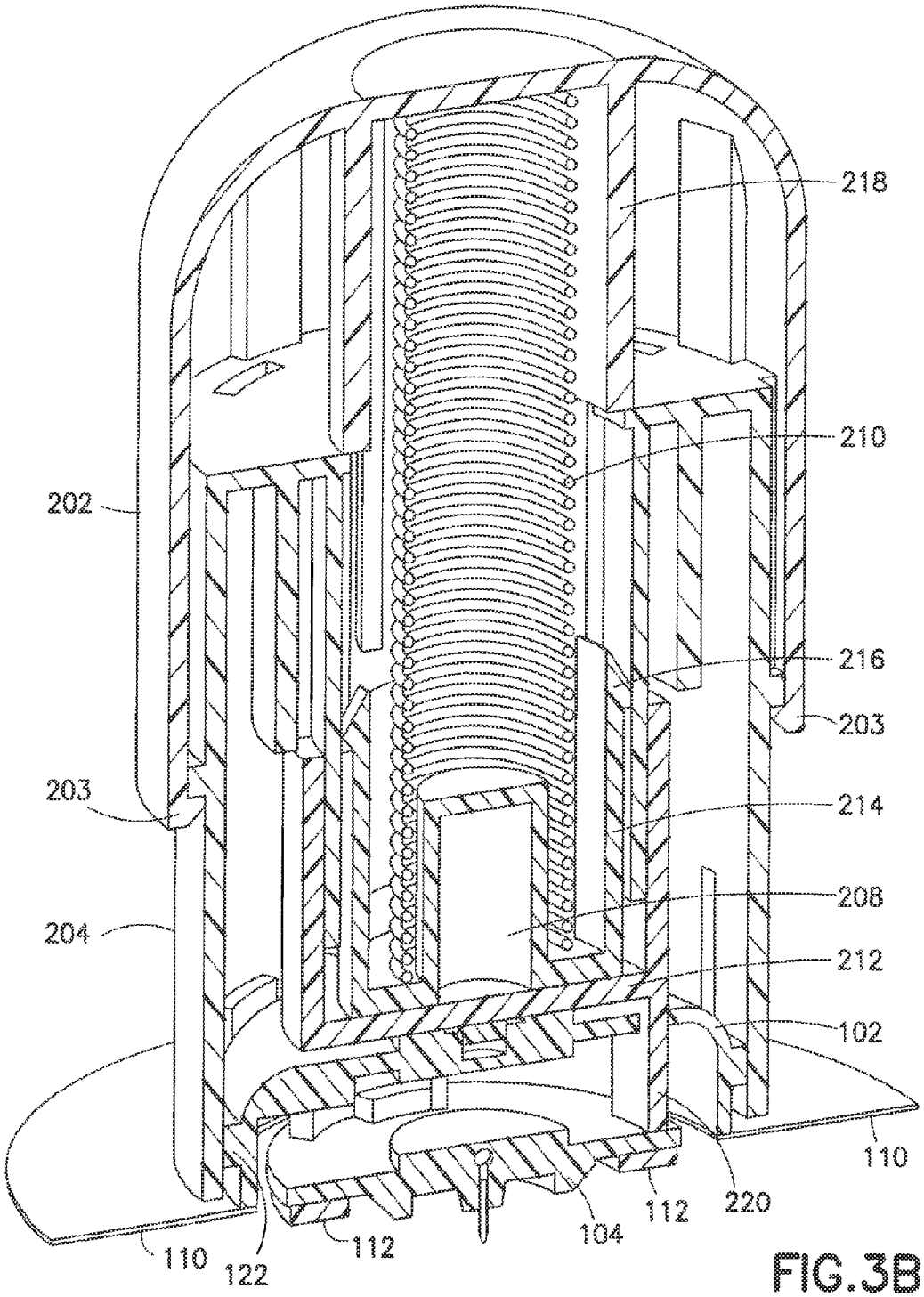
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FIG.3B

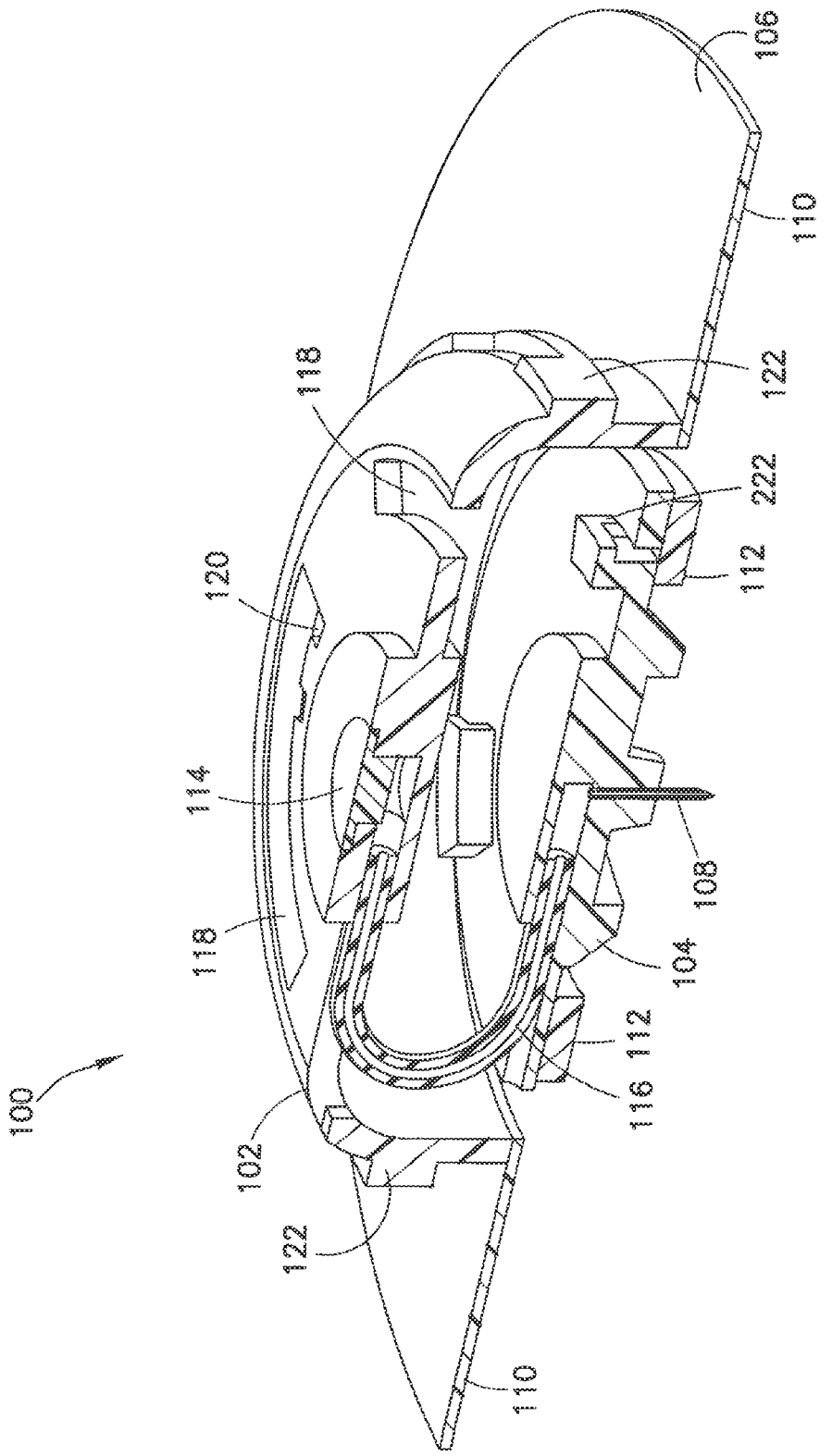
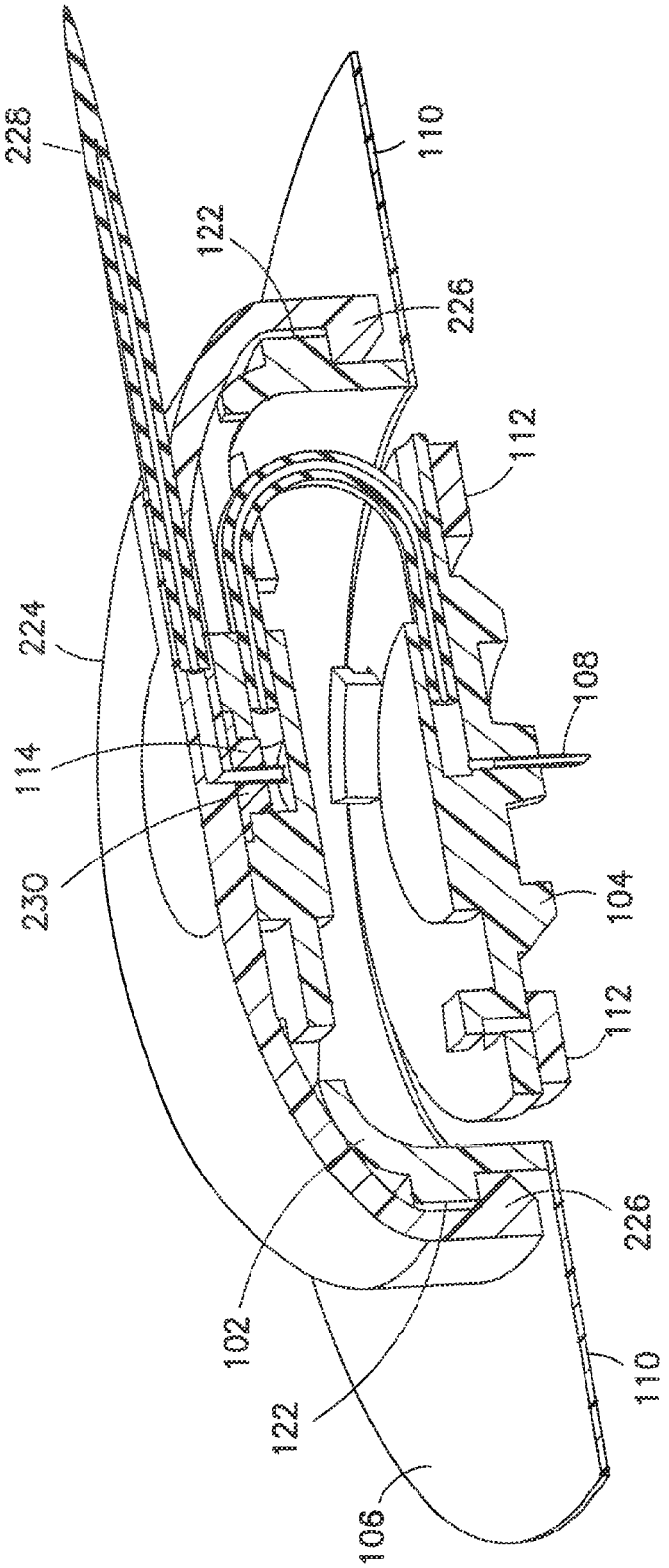


FIG. 4



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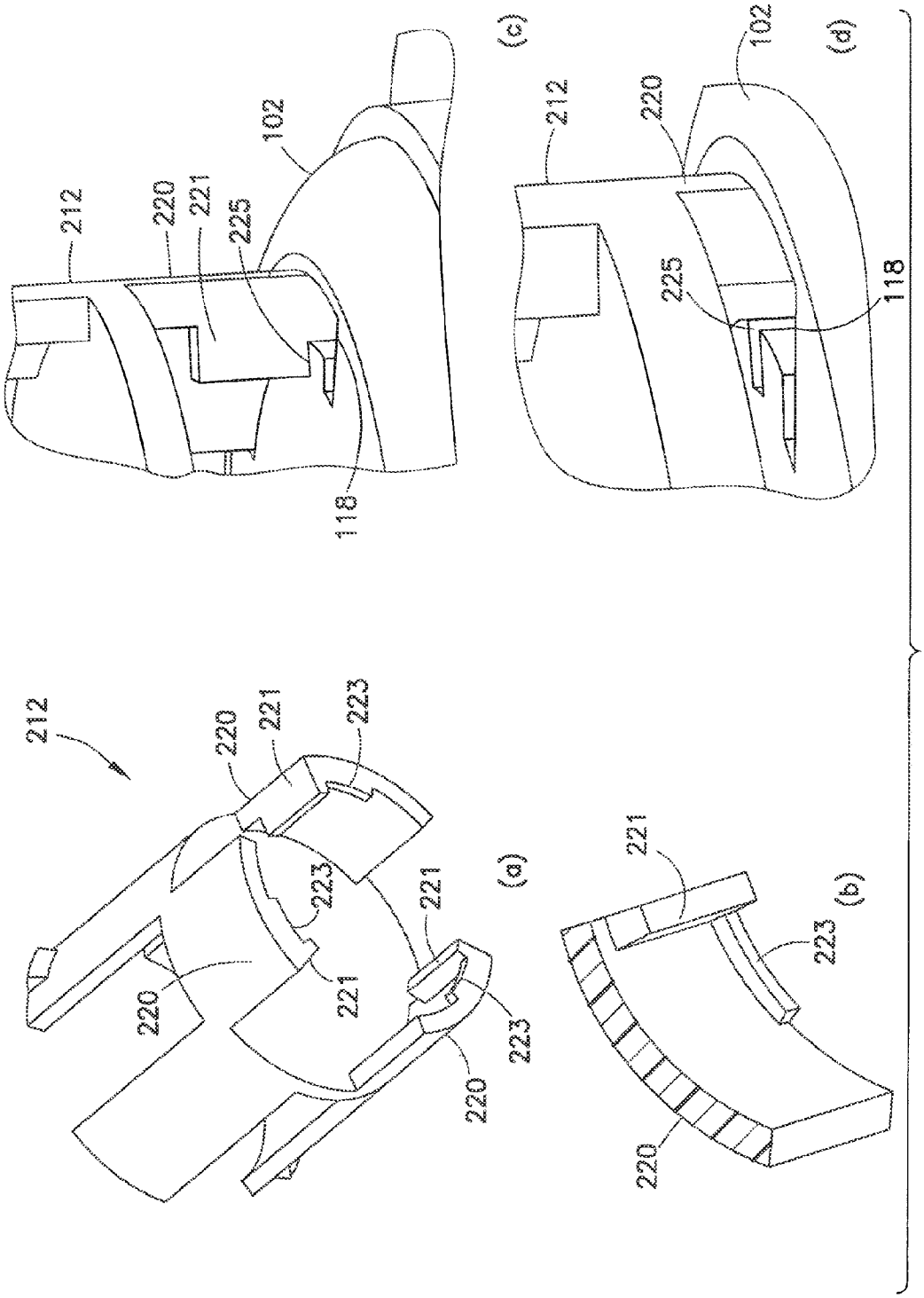
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(b)
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(c)
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225
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118
(d)
212
220
102
225
118

FIG.6

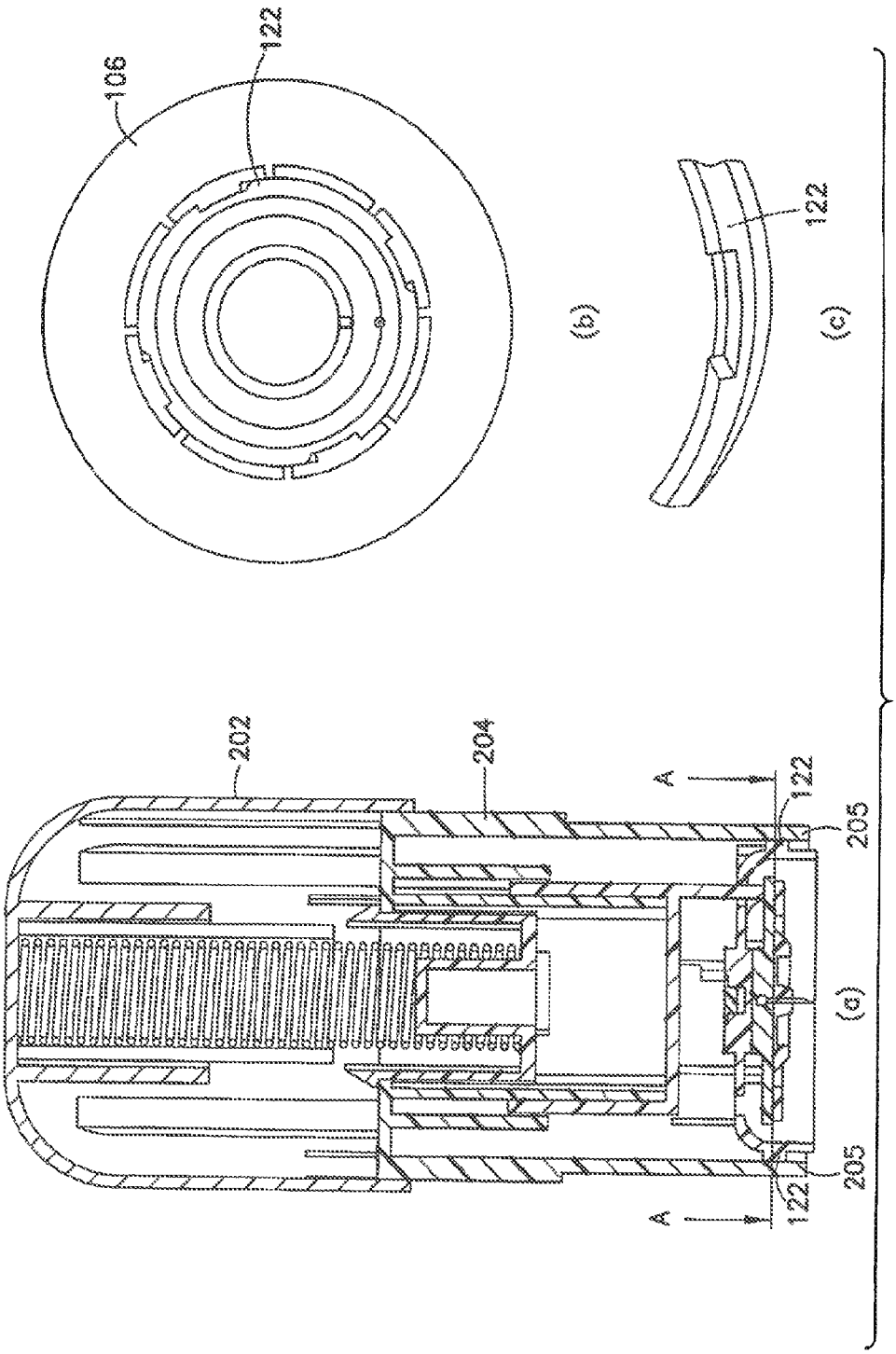

FIG.7

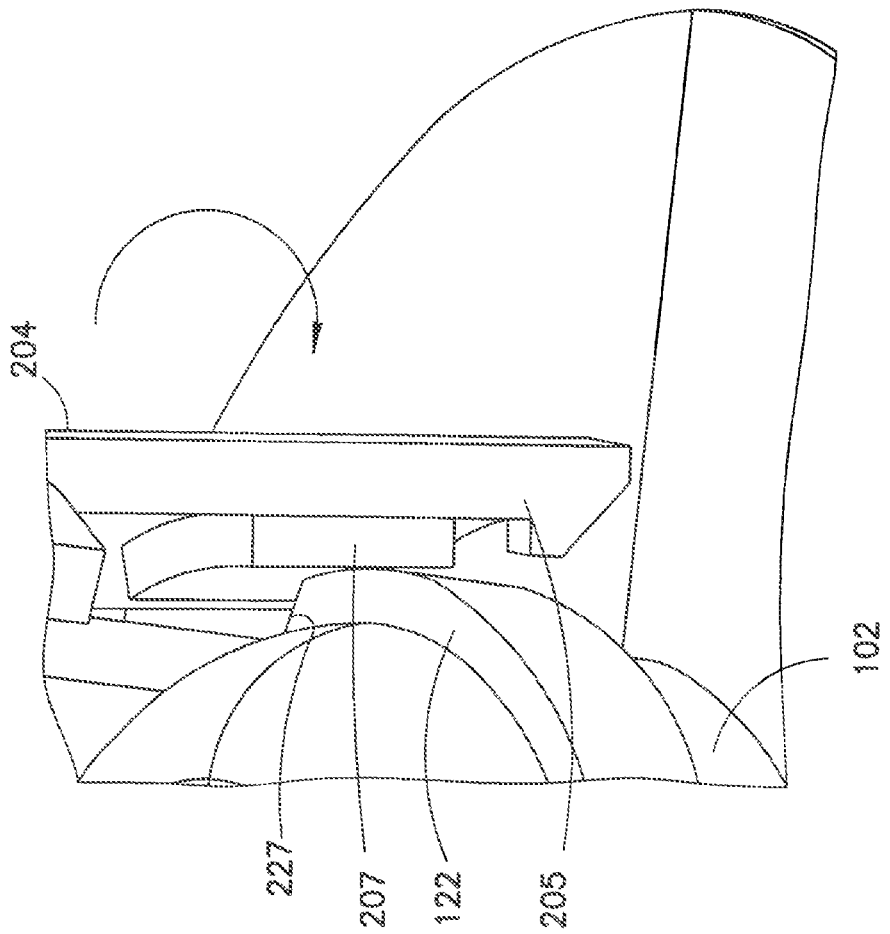

FIG.8

BALLISTIC MICRONEEDLE INFUSION DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of a U.S. patent application of Cole Constantineau et al. entitled "Ballistic Microneedle Infusion System", Ser. No. 13/303,027, filed Nov. 22, 2011, now U.S. Pat. No. 8,814,831, which claims the benefit under 35 U.S.C. §119(e) of a U.S. provisional patent application of Cole Constantineau et al. entitled "Ballistic Microneedle Infusion Device", Ser. No. 61/344,970, filed Nov. 30, 2010, the entire content of both of said prior applications being incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to infusion sets, including a disposable inserter for an infusion set, which ensures proper positioning of insertion by using an adhesive to hold an infusion set in position, and a ballistic inserter releasably coupled with the infusion set to insert a needle at a controlled rate of speed to a desired intradermal depth.

BACKGROUND OF THE INVENTION

A large number of people, including those suffering from conditions such as diabetes use some form of infusion therapy, such as daily insulin infusions to maintain close control of their glucose levels. There are two principal modes of daily insulin therapy. The first mode includes syringes and insulin pens. These devices are simple to use and are relatively low in cost, but they require a needle stick at each injection, typically three to four times per day. The second mode includes infusion pump therapy, which entails the purchase of an insulin pump that lasts for about three years. The initial cost of the pump can be significant, but from a user perspective, the overwhelming majority of patients who have used pumps prefer to remain with pumps for the rest of their lives. This is because infusion pumps, although more complex than syringes and pens, offer the advantages of continuous infusion of insulin, precision dosing and programmable delivery schedules. This results in closer blood glucose control and an improved feeling of wellness.

The use of an infusion pump requires the use of a disposable component, typically referred to as an infusion set or pump set, which conveys the insulin from a reservoir within the pump into the skin of the user. An infusion set typically consists of a pump connector, a length of tubing, and a hub or base from which an infusion needle or cannula extends. The hub or base has an adhesive which retains the base on the skin surface during use, which may be applied to the skin manually or with the aid of a manual or automatic insertion device.

Currently, most insulin infusion sets deliver insulin to the sub-cutaneous layers of skin using either fixed metal needles or flexible plastic cannulas. Such infusion sets typically deliver insulin 4-10 mm below the skin surface. However, the upper 3 mm of skin surface, the intradermal space, facilitates better drug absorption. Unfortunately, due to the relative thinness of the intradermal layer, inserting a needle at such depth and maintaining an infusion site over an extended period of time within this narrow band is difficult.

Further, most insulin infusion sets typically do not provide any features to isolate the inserted needle from shock or other external forces. Since these infusion sets typically deliver insulin 4-10 mm below the skin surface, shock or other external forces to the set have less effect on the deeper inserted needle. However, where an attempt is made to target the upper 3 mm of skin surface, any shock or movement of the set can adversely affect needle insertion and infusion performance.

Still further, most insulin sets have inserters that can result in skin surface "tenting" during needle insertion, where the skin surface is deflected somewhat prior to or during needle insertion which makes precisely targeting the upper 3 mm of skin surface difficult.

Accordingly, a need exists for an infusion set that can deliver content to the upper 3 mm of skin surface, the intradermal space, to facilitate better drug absorption, while maintaining a degree of comfort to the user.

SUMMARY OF THE INVENTION

An object of the present invention is to provide an infusion set which can deliver insulin or other medicament to the upper 3 mm of skin surface, the intradermal space, to facilitate better drug absorption, while maintaining a degree of comfort to the user.

Another object of the present invention is to provide an infusion set having a disposable inserter that can insert a needle at a depth to deliver insulin or other medicament to the upper 3 mm of skin surface.

Another object of the present invention is to provide an infusion set having a disposable inserter that can insert a needle at a controlled high rate of speed to substantially reduce tenting of the skin surface and insert a needle at a depth to deliver insulin or other medicament to the upper 3 mm of skin surface.

Another object of the present invention is to provide an infusion set having a disposable inserter that can be removed, thereby leaving a low-profile infusion set at the infusion site.

Another object of the present invention is to provide an infusion set having a skin securing, adhesive layer to secure the skin surface at the insertion site such that the inserter that can insert a needle without a risk of tenting of the skin surface.

Another object of the present invention is to provide an infusion set that can isolate an inserted needle from external forces such that the needle can be maintained at a depth to deliver insulin or other medicament to the upper 3 mm of skin surface during normal use.

These and other objects are substantially achieved by providing an infusion set having a disposable inserter that can insert a needle at a controlled high rate of speed to a depth to deliver insulin or other medicament to the upper 3 mm of skin surface, and a skin-securing adhesive layer to secure the skin surface at the insertion site such that the inserter that can insert a needle without a risk of tenting of the skin surface. The disposable inserter can be removed, thereby leaving a low-profile infusion set at the infusion site. The position of the inserted needle can be maintained by providing an inner and outer hub of the infusion set that can isolate the inserted needle from external forces such that the needle can be maintained at a depth to deliver insulin or other medicament to the upper 3 mm of skin surface during normal use.

BRIEF DESCRIPTION OF THE DRAWINGS

The various objects, advantages and novel features of the exemplary embodiments of the present invention will be

more readily appreciated from the following detailed description when read in conjunction with the appended drawings, in which:

FIG. **1** is a perspective view of an infusion set and a disposable ballistic inserter in an assembled position in accordance with an embodiment of the present invention;

FIG. **2** is a bottom perspective view of the infusion set and disposable ballistic inserter of FIG. **1** in accordance with an embodiment of the present invention;

FIG. **3**A is a cross-sectional view of the infusion set and disposable ballistic inserter of FIG. **1** prior to activation, in accordance with an embodiment of the present invention;

FIG. **3**B is a cross-sectional view of the infusion set and disposable ballistic inserter of FIG. **1** after activation, in accordance with an embodiment of the present invention;

FIG. **4** is a cross-sectional view of the infusion set after activation and removal of the disposable ballistic inserter but prior to attachment to the infusion pump tube attachment, in accordance with an embodiment of the present invention;

FIG. **5** is a cross-sectional view of the infusion set after activation and attachment to the infusion pump tube attachment, in accordance with an embodiment of the present invention;

FIG. **6** is a set of enlarged views of the table of the infusion set of FIG. **1**, in accordance with an embodiment of the present invention;

FIG. **7** is a set of enlarged sectional views of the lower inserter housing of the disposable ballistic inserter and the infusion set, in accordance with an embodiment of the present invention; and

FIG. **8** is an enlarged view of the lower inserter housing of the disposable ballistic inserter being deflected away and released from the infusion set, in accordance with an embodiment of the present invention.

Throughout the drawings, like reference numerals will be understood to refer to like parts, components and structures.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

The exemplary embodiments of the present invention deliver insulin or other medicament to the intradermal layers of the skin via a standard insulin pump or other similar device. By utilizing a disposable ballistic inserter, a skin securing adhesive, and an isolated inner hub, proper insertion and maintenance of the inserted needle in the intradermal space is ensured using a low profile set, while maintaining a degree of comfort to the user.

The exemplary embodiments of the present invention provide an exemplary infusion set having a disposable ballistic inserter that can insert a needle at a depth to deliver content to the upper 3 mm of skin surface. To do so, the exemplary embodiments comprise a disposable ballistic inserter that can insert a needle of an infusion set at a controlled high rate of speed to substantially reduce tenting of the skin surface and insert the needle at a depth to deliver insulin or other medicament to the upper 3 mm of skin surface. The disposable ballistic inserter can be removed, thereby leaving a low-profile infusion set at the infusion site. The infusion set is also provided with at least one skin securing, adhesive layer to secure the infusion set to the skin surface at the insertion site, such that the ballistic inserter when activated by the user is at the correct position relative to the skin surface, and such that the skin is secured during insertion to further aid needle insertion without a risk of tenting of the skin surface. The infusion set is still further provided with an inner and outer hub that can isolate an inserted needle from external forces such that the needle can be maintained at a depth to deliver content to the upper 3 mm of skin surface during normal use.

FIGS. **1** and **2** are perspective views of an infusion set and a disposable ballistic inserter in an assembled configuration in accordance with an embodiment of the present invention, and FIG. **3**A is a cross-sectional view of the infusion set and disposable ballistic inserter of FIG. **1** prior to activation. In a preferred embodiment, the infusion set and disposable ballistic inserter are received by the user in the assembled configuration, but embodiments of the present invention are not limited thereto.

As shown in FIGS. **1**, **2** and **3**A, the infusion set **100** is releasably secured to the disposable ballistic inserter **200** for placement of the infusion set and insertion of a needle or cannula into a skin surface. To do so, the infusion set **100** can comprise an outer hub **102**, an inner hub **104** (i.e., needle hub), and a surrounding member **106**. The inner hub **104** can comprise at least one needle **108**. The needle **108** can preferably comprise a 34 gauge, single-bevel stainless steel needle/cannula, but embodiments are not limited thereto. In yet other embodiments of the present invention, the needle **108** can be plastic or other material, between 25 gauge and 36 gauge, and be provided with a tri-bevel or 5-bevel, and be between 1.0 and 10 mm long, but embodiments are not limited thereto. The needle **108** can be bonded to the inner hub **104** with an adhesive, such as a Loctite/UV cured adhesive, or can be over molded with, or threaded into the inner hub **104**. The surrounding member **106** can comprise an outer skin adhesive **110**, and the inner hub **104** can comprise an inner skin adhesive **112**. In exemplary embodiments of the present invention described below, the hubs and other elements can be constructed of a molded plastic material, polycarbonate, thermoplastic polymer such as polyethylene terephthalate (PET and PETG), or similar materials.

As shown in greater detail in FIG. **4**, the outer hub **102** of the infusion set **100** comprises a low-profile, substantially circular, dome shape with rounded edges and a number of features to releasably secure the ballistic inserter **200** and after removal thereof, releasably secure a tube set connection. To do so, the upper surface of the outer hub **102** comprises a septum/valve connection **114** for connection with a tube set connector after removal of the ballistic inserter **200**. The connection **114** is connected to the inner hub **104** via at least one flexible tubing **116**. In an exemplary embodiment of the present invention, the inner hub **104** is connected to the outer hub **102** solely through the flexible tubing **116** after removal of the ballistic inserter **200**. Prior to insertion, the inner hub **104** is held within the outer hub **102** by a table **212** as described in greater detail below. After activation, the inner hub **104** is held in place by the inner skin adhesive **112**, and is connected to the outer hub **102** through the flexible tubing **116**.

As further shown in FIG. **4**, the outer hub **102** has a diameter which can releasably fit within an opening of the ballistic inserter **200** as described in greater detail below. The upper surface of the outer hub **102** still further comprises one or more arcuate openings **118** positioned over the inner hub **104**. In doing so, arms **220** of the table **212** of the ballistic inserter **200** can pass through the outer hub **102** and contact and secure the inner hub **104**. Further, the arcuate form of the openings **118** allow rotation of the arms **220** of the table **212**, and one or more gaps **120** in the openings **118** can permit the arms of the table **212** to be pulled free from the outer hub **102** of the infusion set **100** and discarded as described in greater detail below.

The outer hub **102** still further comprises a stepped rail **122** around an outer circumference for releasably securing the ballistic inserter **200** to the infusion set **100**. The stepped rail **122** is provided as a guidance feature to align travel in the normal direction after impact. Further, the stepped rail **122** comprises chamfers that are configured to allow the lower inserter housing **204** to be rotated clockwise as described in greater detail below. Rotating the lower inserter housing **204** causes attachment arms of the lower inserter housing **204** to flex out, thereby allowing the ballistic inserter **200** to be removed from the infusion set **100**.

Returning to FIGS. **1**, **2** and **3**A, the ballistic inserter **200** comprises a button **202** slidably coupled to a lower inserter housing **204**. The button **202** is configured to slidably engage the lower inserter housing **204** as guided by one or more tracks **206** on an outer surface of the lower inserter housing **204**. A ballistic hammer **208** is captured within the assembled button **202** and lower inserter housing **204**, and is configured to be driven downward by a spring **210**. The table **212** is positioned within the lower inserter housing **204** to extend through the outer hub **102** of the infusion set **100** as described above, and to contact and secure the inner hub **104**. Prior to insertion, the inner hub **104** is held within the outer hub **102** by the table **212**. To do so, the table **212** is releasably locked to the inner hub **104** via one or more arms **220** which protrude through openings **118** of the outer hub **102**, and capture detents **222** on an upper surface of the inner hub **104**. The arms **220** of the table **212** can be released from the detents **222** of the inner hub **104** by a twisting motion as described in greater detail below.

The button **202** captures the spring **210** between a closed upper button surface within member **218** and the hammer **208**. In doing so, the spring **210** is configured to urge the hammer **208** downward upon loading and release of the hammer. However, prior to activation, the hammer **208** is held from downward movement by one or more arms **214** and inclined detents **216** thereon, held by an opening in the lower inserter housing **204**.

Accordingly, downward movement of the button **202** serves to first compress the spring **210**. At or near an end of downward travel of the button **202**, member **218** of the button **202** contact the inclined detents **216** of the hammer **208**, which releases the one or more arms **214** and inclined detents **216** from the opening in the lower inserter housing **204** and the hammer **208** is released and urged downward by the spring **210**. The button **202** is then locked to the lower inserter housing **204** at this point via button snaps **203** capturing detents on the lower inserter housing **204** as shown in FIG. **3**B.

Once released by the button **202**, the hammer **208** is urged downward and strikes the table **212**. The struck table **212** now moves downward and the arms **220** of the table **212** extending through the outer hub **102** moves the inner hub **104** and needle **108** downward such that the inner hub **104** is placed at the infusion site, secured via adhesive **112**, and needle **108** is inserted. In doing so, the inner hub **104** and needle **108** are driven into the skin surface at a controlled high rate of speed, of 3.3 ft/sec. (1.0 m/sec.) up to and including those greater than 10 ft/sec. (3.0 m/sec.), which minimizes the risk of tenting at needle insertion. By using such a driving spring, a high-speed insertion is achieved which is considered more reliable for insertion of short (i.e., 1.5 mm) needle or cannula.

As noted above, precise insertion is achieved by first securing the infusion set **100** to the infusion site via the adhesive **110**, which permits the user to activate the disposable ballistic inserter **200** at the proper alignment as described above, and insert the needle. In doing so, the needle is driven into the skin surface at a controlled high rate of speed to minimize the risk of tenting at needle insertion. Further, the adhesive **110** at or very near the insertion site secures the skin surface and further minimizes tenting of the skin surface during insertion.

After insertion, the user can then turn or twist the ballistic inserter **200** relative to the secured infusion set **100** for release. Specifically, the infusion set **100** is secured to the infusion site via the adhesive **110** and **112**, which permits the user to turn the ballistic inserter **200** relative to the set **100** for release without affecting infusion set position, such that the rail **122** and openings **118** and **120** of the outer hub **102** allow the release and removal of the disposable ballistic inserter **200**. Specifically, the arms **220** of the table member **212** of the ballistic inserter **200** pass through the outer hub **102** and contact and secure the inner hub **104**. The table **212** is releasably locked to the inner hub **104** via arms **220** which protrude through openings **118** of the outer hub **102**, and capture detents **222** on an upper surface of the inner hub **104**. The arms **220** of the table **212** can be released from the detents **222** of the inner hub **104** by a twisting motion. The arcuate form of the openings **118** allow rotation of the arms **220** of the table **212**, and gaps **120** in the openings **118** permit the arms **220** of the table **212** to be pulled free from the outer hub **102** of the infusion set **100**. Further, rotating the lower inserter housing **204** causes attachment arms of the lower inserter housing **204** to flex out, thereby allowing the ballistic inserter **200** to be removed from the infusion set **100**.

In an exemplary use of the embodiments of the present invention, proper insertion of the infusion set **100** into the delivery site consists of three straightforward steps. First, the infusion set **100** and ballistic inserter **200** are positioned and used to insert the needle **108** into the intradermal layers of the skin. To do so, an adhesive covering backing (not shown) if provided, can be peeled off one or both of the skin adhesive layers **110** and **112** of the infusion set **100**, and the infusion set **100** is adhered to the skin surface in the area of the desired infusion site. The user then presses downward on the inserter button **202**, loading the spring **208**, releasing the hammer **208** to strike the table **212**, which moves the inner hub **104**, placing the inner hub **104** of the infusion set at the infusion site and inserting the needle **108** into the skin surface of the infusion site.

Second, the ballistic inserter **200** is removed from the infusion set **100** with a twisting motion and then discarded, leaving the low-profile infusion set **100** in place. As shown in FIG. **4**, the infusion set **100** is then exposed to receive the tube set connection (not shown). Once in position, the inner hub **104** is fully enclosed by the outer hub **102**, and is connected to the outer hub **102** solely through the flexible tubing **116** after removal of the ballistic inserter **200**. Further, the inner hub is adhesively secured to the skin surface using the adhesive layer **112** that is separate from the adhesive layer **110** securing the outer hub **102** to the skin surface. Third, the user can then attach the tube set connection as shown in FIG. **5** to the valve connection **114** of the outer hub **102** using one or more of the features used to secure the ballistic inserter **200** to the infusion set **100**. FIG. **5** is a cross-sectional view of the infusion set after activation and attachment to the infusion pump tube attachment, in accordance with an embodiment of the present invention.

As shown in FIG. **5**, the infusion pump tube attachment **224** can comprise a substantially dome-shaped component to cover, enclose and secure with the outer hub **102**. To do so, the exemplary attachment **224** comprises a dome-shaped

component having an opening to receive the outer hub **102**, and includes connector snaps **226** to attach the infusion pump tube attachment **224** to the stepped rail **122** of the outer hub **102** similar to the connection with the ballistic inserter **200**. Release of the infusion pump tube attachment **224** can also be performed in a manner similar to the release of the ballistic inserter **200**, wherein a turning motion of the attachment **224** deflects the connector snaps **226** from the stepped rail **122** of the outer hub **102** and releases the infusion pump tube attachment **224**. Further, the infusion pump tube attachment **224** can be provided with a connector needle or cannula **230** for piercing the septum/valve connection **114** of the outer hub **102**, and can be provided with the tube **228** for connection with an infusion pump (not shown).

The user can prime the pump tube attachment **224** prior to attachment to the infusion set **100**, and then deliver insulin or other medicament to the infusion site via the attached infusion pump (not shown).

Inside the exemplary device, the inner hub **104** is entirely contained within the outer hub **102**, and the ballistic inserter **200** can be connected to the inner hub **104** through openings in the outer hub **102**. As noted above, the ballistic inserter **200** comprises the button **202**, spring **210**, hammer **208** and table **212**. Accordingly, as the user presses downward on the inserter button **202**, the spring **210** is loaded up against the hammer **208**, which is snapped to the lower inserter housing **204**. When the spring **210** is frilly compressed, the same downward motion unlatches the hammer snaps of arms **214**, and the button **202** is locked into the lower inserter housing **204**.

The spring **210** is compressed until it gains a maximum potential energy. This energy is determined by calculating the torsional stresses built up in the spring as it is compressed. By calculating potential energy, and the kinetic energy at the point of needle insertion, an insertion velocity can be calculated. In an exemplary embodiment of the present invention, the spring **210** is configured to insert an exemplary needle at a controlled high rate of speed, of 3.3 ft/sec. (1.0 m/sec.) up to and including those greater than 10 ft/sec. (3.0 m/sec.). Depending upon cannula sharpness, a high terminal velocity produces more reliable results for intradermal insertions of short (i.e., 1.5 mm) needle or cannula.

When the hammer snaps of arms **214** are unlatched, the hammer **208** is propelled downward by the spring **210** toward the table **212**. The table **212** is releasably locked to the inner hub **104** via one or more arms **220** which protrude through the outer hub **102**. When the hammer **208** collides with the table **212**, the inner hub **104** moves downward, adheres to the skin surface, and pierces the skin surface with the needle **108**.

Prior to insertion, the table **212** prevents rotation of the ballistic inserter **200** with respect to the outer hub **102**. FIG. **6** is a set of enlarged views of the table of the infusion set of FIG. **1**, in accordance with an embodiment of the present invention. As shown in FIG. **6**(*a*), the table **212** comprises on or more arms **220** having a number of features thereon. For example, the arms **220** comprise a vertical face member **221** to prevent rotation relative to the outer hub **102** before insertion as shown in FIG. **6**(*c*). The members **221** are caught by openings **225** in the outer hub **102**. After insertion, members **221** are below openings **225** in the outer hub **102**, such that the table **212** is free to rotate relative to the outer hub **102** as shown in FIG. **6**(*d*). The arms **220** further comprise one or more undercuts **223** which are configured to capture the detents **222** on the upper surface of the inner hub **104**. The arms **220** of the table **212** can be released from the detents **222** of the inner hub **104** after insertion, by the same twisting motion that releases the lower inserter housing **204** from the set as described above.

After the needle **108** is inserted, and the table **212** and inner hub **104** are in a down position, the user can turn the ballistic inserter **200** clockwise), and the table **212** rotationally slides away from the inner hub **104** which is locked to the skin surface via the adhesive layer **112**. This turning motion also flexes the lower inserter housing **204** snaps **205** outward, away from the outer hub **102**. As described above and shown in FIGS. **7**(*a*), **7**(*b*) and **7**(*c*), and in FIG. **8**, the outer hub **102** comprises the stepped rail **122** with chamfers around an outer circumference for releasably securing the ballistic inserter **200** to the infusion set **100**, and for later releasably securing the infusion pump tube attachment **224** with the outer hub **102**. To do so, the lower inserter housing **204** comprises attachment arms with snaps **205** for securing the lower inserter housing **204** to the rail **122** of the outer hub **102**. The lower inserter housing **204** further comprises elements **207** which are configured to engage the chamfers **227** of the rail **122**. In doing so, the stepped rail **122** is configured to allow the lower inserter housing **204** to be rotated (e.g., clockwise) which causes the attachment arms of snaps **205** of the lower inserter housing **204** to flex out as urged by contact with the chamfers **227** of the rail **122**, thereby allowing the inserter **200** to be removed from the set **100**. The user can now pull off the ballistic inserter **200** for disposal.

Accordingly, a simple rotational and vertical motion can be used to release the ballistic inserter **200**. Potentially, a rotational unlocking motion can cause an infusion set to peel off the skin surface if the user twists the entire assembly at an angle. Disconnecting the ballistic inserter **200** from the outer hub **102** after the down stroke of the button **202** minimizes this risk, and is more ergonomic and reliable.

To ensure shock isolation of the inner hub **104**, the inner hub **104** is fully enclosed by the outer hub **102**, and is connected to the outer hub **102** solely through the flexible tubing **116** after removal of the ballistic inserter **200**. Further, the inner hub is adhesively secured to the skin surface using the adhesive layer **112** that is separate from the adhesive layer **110** securing the outer hub **102** to the skin surface. The inner hub **104** has a separate adhesive, and is connected to the outer hub **102** via only the flexible tube **116**, such that the inner hub **104** is protected from external vibrations and forces. In the exemplary embodiment shown, the flexible tubing **116** at least partially loops upward (on the vertical) between the inner hub **104** and the outer hub **102**, which permits a smaller footprint device profile. As noted above, the inner hub **104** is connected to the outer hub **102** solely through the flexible tubing **116**. Prior to insertion, the inner hub **104** is held within the outer hub **102** by the table **212**. After activation and release and removal of the table **212**, the inner hub **104** is held in place by the inner skin adhesive **112** beneath the inner hub **104**, and is connected to the outer hub **102** through the flexible tubing **116**. The tube set connection **224** can then be snapped over the same features which held the ballistic inserter **200**, and rotated to allow for comfortable pump tube routing.

In the disclosed arrangement, the needle **108** is protected from external forces and vibrations by the outer hub **102**, and the isolation of the inner hub **104**. By carefully isolating the inner hub **104** and the needle **108** from external forces, the needle position within the intradermal layer is maintained.

Further, the arrangement of the assembled set **100** and ballistic inserter **200** ensure proper alignment and positioning. Most existing inserters are either oversized, to ensure an insertion force perpendicular to the skin surface, or are thin and portable, which can lead to misaligned insertion. In the exemplary embodiments of the present invention, by first adhering or "locking" the outer skin adhesive **110** of the infusion set **100** to the skin surface, the ballistic inserter **200** is aligned properly for needle insertion. Accordingly, the exemplary embodiments of the present invention can include a relatively small inserter which is properly aligned with the infusion site at a time of use.

Such a system and method further allows the use of a small intradermal needle, or microneedle, which can be placed perpendicular to the skin surface, and which is isolated from outside forces, thereby maintaining position and causing less pain to the user during use. Still further, by infusing into the intradermal layer of the skin, the exemplary embodiments of the present invention offer the potential for better absorption of insulin when compared to subcutaneous delivery systems. In doing so, it may be possible for the typical user to both consume less insulin and maintain a better medicament regime. It will be appreciated that multiple needles or microneedles can be used, if desired, in place of a single needle or microneedle.

As noted above, intradermal infusion sets are at risk of tenting, which is the undesired effect where skin is deflected at or during insertion, creating a shape associated with a tent. In doing so, the skin surface tents during needle insertion rather than needle penetration into the skin. However, since the present invention provides a needle which is inserted at a controlled high rate of speed, of 3.3 ft/sec. (1.0 m/sec) up to and including those greater than 10 ft/sec., and wherein the skin surface is secured at and/or near the insertion site, the exemplary embodiments of the present invention do not present such a risk and ensure more precise needle insertion depth.

In existing steel cannula infusion sets which deliver insulin to the subcutaneous layer, the needle is not isolated from any undesired outside forces which may cause pain when translated to the needle and the needle moves within the skin. Also, other intradermal devices face problems of premature or otherwise undesired needle removal when the device is bumped if the needle is not isolated form the outside forces.

In the exemplary embodiments of the present invention, the intradermal needle is isolated from outside forces by at least three features. First, the outer hub **102** shields the sensitive inner hub **104** from direct contact with external forces. Second, the inner hub **104** and outer hub **102** are secured to the infusion site via separate adhesive segments. Third, the connection between the outer hub **102** and the inner hub **104** is extremely flexible, so that any forces imparted on the protective outer hub **102** do not carry over to the needle **108**. For example, the provision of the flexible tubing connection **116**, along with the outer hub **102**, serves to effectively isolate the needle **108** from the outside forces and other interference.

Proper inserter alignment is accomplished by providing a solid, fixed foundation for the user to press the inserter button. Such a solid, fixed foundation is provided by the surrounding member **106**, outer skin adhesive **110**, and the inner skin adhesive **112**. The skin adhesive layers secure the set **100** at a desired orientation, such that the attached ballistic inserter **200** is also at a desired orientation of use, and the user is substantially prevented from holding the inserter at angles to the insertion site. Accordingly, precise, repeatable insertions are accomplished via the pre-adhesion of the outer hub **102**. By fixing a ring of skin around the actual insertion site, movement of the skin surface relative to the inner hub are reduced.

Existing infusion sets sometimes require the use of a separate inserter. In the exemplary embodiments of the present invention described herein, the user does not have to carry a separate inserter or load the infusion set onto an inserter. The integrated system allows the user more freedom from carrying and loading a separate inserter resulting in improved convenience and simpler operation.

Although only a few exemplary embodiments of the present invention have been described in detail above, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the appended claims and their equivalents.

What is claimed is:

1. An infusion system, comprising:
an infusion set and an inserter, wherein:
said infusion set comprises an inner hub and an outer hub configured to receive a tube for connection to an infusion pump;
at least one of said inner hub and said outer hub is releasably secured by said inserter;
said inserter comprises an inserter button and a spring;
said inserter button is configured to release said spring and drive said infusion set for placement at an infusion site; and
activation of said inserter button sequentially compresses said spring to create a driving force and releases said spring to trigger said inserter.

2. The infusion system as recited in claim **1**, further comprising a flexible tube coupled between said inner hub and said outer hub and providing a fluid communication path therebetween.

3. The infusion system as recited in claim **1**, wherein said spring is configured to place said infusion set at a controlled rate of speed of at least 3.3 ft/sec. (1.0 m/sec.).

4. An infusion system, comprising:
an infusion set and an inserter, wherein:
said infusion set comprises an inner hub and an outer hub configured to receive a tube for connection to an infusion pump;
at least one of said inner hub and said outer hub is releasably secured by said inserter;
said inserter comprises an inserter button and a spring;
said inserter button is configured to release said s and drive said infusion set for placement at an infusion site; and
activation of said inserter button sequentially compresses said spring and releases said spring to trigger said inserter, and further comprising:
a first adhesive layer disposed on a surface of said inner hub; and
a second adhesive layer disposed on a surface of said outer hub, wherein said first adhesive layer is separate from said second adhesive layer.

5. An infusion system, comprising:
an infusion set and an inserter, wherein:
said infusion set comprises an inner hub and an outer hub configured to receive a tube for connection to an infusion pump;
at least one of said inner hub and said outer hub is releasably secured by said inserter;

said inserter comprises an inserter button and a spring;

said inserter button is configured to release said spring and drive said infusion set or placement at an infusion site; and

activation of said inserter button sequentially compresses said spring and releases said spring to trigger said inserter, and further comprising:

a hammer disposed at an end of said spring and configured for release by movement of said inserter button; and

a table rotationally secured to said inner hub and configured to be struck by said hammer.

6. The infusion system as recited in claim **5**, wherein said table is configured to releasably secure said inner hub in a retracted position within said outer hub.

7. The infusion system as recited in claim **5**, wherein:

said table comprises a first detent; and

said inner hub comprises second detent, wherein said first detent is configured to rotationally engage with said second detent to releasably secure said table with said inner hub.

8. The infusion system as recited in claim **7**, wherein:

said outer hub comprises a third detent; and

said lower inserter housing comprises a fourth detent, wherein said third detent is configured to rotationally engage with said fourth detent to releasably secure said inserter with said outer hub.

9. An infusion system, comprising:

an infusion set and an inserter, wherein:

said infusion set comprises an inner hub and an outer hub configured to receive a tube for connection to an infusion pump;

at least one of said inner hub and said outer hub is releasably secured by said inserter;

said inserter comprises an inserter button and a string;

said inserter button is configured to release said spring and drive said infusion set for placement at an infusion site;

activation of said inserter button sequentially compresses said spring and releases said spring to trigger said inserter; and

said inserter further comprises a lower inserter housing, slidably coupled with said inserter button, and rigidly coupled with said outer hub.

10. An inserter, comprising:

an inserter button and a lower inserter housing slidably coupled with said inserter button and configured to be coupled with an infusion set; and

a spring captured between said inserter button and said lower inserter housing;

wherein said inserter button is configured to release said spring to drive said infusion set for placement at an infusion site;

wherein activation of said inserter button sequentially compresses said spring to create a driving force and releases said spring to trigger said inserter; and

wherein said infusion set comprises a hub configured to receive a tube for connection to an infusion pump.

11. The inserter as recited in claim **10**, wherein said spring is configured to place said infusion set at a controlled rate of speed of at least 3.3 ft/sec. (1.0 m/sec.).

12. An infusion set, comprising:

an inner hub and a first adhesive layer disposed on a surface of said inner hub;

an outer hub; and

a second adhesive layer disposed on a surface of said outer hub, wherein said first adhesive layer is separate from said second adhesive layer;

wherein at least one of said inner hub and said outer hub is releasably secured by an inserter having an inserter button and a spring; and

wherein activation of said inserter button sequentially compresses said spring and releases said spring to trigger said inserter.

13. The infusion set as recited in claim **12**, further comprising a flexible tube coupled between said inner hub and said outer hub and providing a fluid communication path therebetween.

14. The infusion set as recited in claim **12**, wherein:

said inner hub comprises first detent, wherein said first detent is configured to rotationally engage with a detent of an inserter to releasably secure said inserter with said inner hub; and

said outer hub comprises a second detent, wherein said second detent is configured to rotationally engage with a detent of said inserter to releasably secure said inserter with said outer hub.

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